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| 09/554,793      | 09/19/2000  | Volker Zimmer        | RDID0043US          | 1444             |

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EXAMINER

QUAN, ELIZABETH S

ART UNIT PAPER NUMBER

1743

DATE MAILED: 11/24/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

CH019

|                              |                               |                                |  |
|------------------------------|-------------------------------|--------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>09/554,793 | Applicant(s)<br>ZIMMER, VOLKER |  |
|                              | Examiner<br>Elizabeth Quan    | Art Unit<br>1743               |  |

-- Th MAILING DATE of this communication appears on th cov r sheet with the correspond nce address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-5, 7 and 9-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7, and 9-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 17-22, 24, 25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,399,316 to Yamada.

Referring to claims 17-19, 21, 22, 24, 25, Yamada discloses a device (10) for withdrawing samples of liquid for analytical elements (see ABSTRACT; FIGURE). The device (10) comprises a carrier (17), detection element, cover (11) with a surface that cooperates with a

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surface of the carrier (17) to form a capillary-active channel (14), second cover (24), and intermediate layer (12,13) positioned between the second cover (24) and carrier (11) (see FIGURE). Since the instant specification on page 11, lines 4 and 5 discloses that the detection element (2) may be a reagent-impregnated membrane, the detection element may be considered the specific affinity material placed in the reaction region (21) (see COL. 6, lines 55 and 56). The specific affinity material may be chemically or physically bound to at least one surface of the cover (11), intermediate layers (12,13), or carrier (17) (see COL. 6, lines 56-59). Alternatively, an insoluble material to which a specific affinity material is bound may be placed in the reaction region (21) so as not to interfere with the flow of the solution inside the capillary-active channel (14) (see COL. 6, lines 59-63). In this case, one would expect that the insoluble material would have opposite first and second ends with the first end being positioned adjacent to the carrier. Since the specific affinity material is placed in the channel (14), one would also expect that the cover (11) would also cooperate with a surface of the detection element to form the channel (14). After sufficient time has passed for a reaction to occur, a detection unit of a measuring apparatus, such as a photoelectron multiplier is located above the carrier (17), which covers the reaction region (21), and the amount of light emitted from the reaction region (21) is measured (see COL. 7, line 67-COL. 8, line 44). In the event one would argue that the specific affinity material is not an element distinct from the cover as shown in the drawings of the instant application, it would have been obvious to one having ordinary skill in the art at the time the invention was made to separate the specific affinity material from the cover since it provides flexibility in testing different assays by allowing placement of different specific affinity material to be placed into the reaction region especially when the device is disclosed as reusable (see COL. 7,

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lines 26-41). Furthermore, it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art (*Nerwin v. Erlichman*, 168 USPQ 177,179).

The channel (14) has a sample application opening (22) defined by at least one edge (see FIGURE). The channel (14) extends at least from the opening to the second end of the detection element since excess liquid is absorbed by member (28), an ancillary element that may be attached to the end of the channel (14) or second end of the reaction region (21) (see FIGURE). The at least one notch (15,16) in the form of a partial groove is positioned at the at least one edge of the sample application opening (22) of the channel (14) such that one side of the edge of the sample application opening (22) is at least partially interrupted by the at least one notch (15,16) and the surface facing opposite to the at least one notch (15,16) facing the channel (14) is exposed. A liquid sample is contacted with the edge of the sample application opening (22) adjacent to the notch (15,16) such that the liquid sample is immediately transported by capillary forces into the channel (14) (see ABSTRACT; FIGURE; SUMMARY OF THE INVENTION; COL. 5, lines 13-31; COL. 6, lines 64-68; COL. 7, lines 1-68; COL. 8, lines 1-9 and 14-36).

Referring to claim 20, according to Merriam-Webster Collegiate Dictionary, stagger is defined as to arrange in any of various zigzags, alternations, or overlappings of position or time, and alternations is defined as causing to alternate, which is defined as arranged first on one side and then on the other at different levels or points along an axial line or arranged one above or alongside the other. It is noted that the two notches (15,16) are arranged one above or alongside the other depending on the frame of reference and inherently arranged first on one side and then on the other at different levels or points along an axial line, as imperfections inherently exist.

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4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,399,316 to Yamada in view of U.S. Patent No. 4,439,526 to Columbus.

Referring to claim 19, Yamada does not disclose at least two notches next to each other. However, in the field of capillary fluid flow, it is known to provide a plurality of access means to the capillary to facilitate fluid flow into the capillary channel. See, for example, Columbus, abstract; column 2, lines 29-46 and column 6, lines 63 through column 7, line 2. It would have been obvious to one of ordinary skill in the art to provide at least 2 notches (access means) at the entrance of the channel in the device of Yamada in order to facilitate fluid flow in the channel.

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,399,316 to Yamada in view of U.S. Patent No. 6,238,624 to Heller et al.

Referring to claim 23, Yamada does not disclose using oxidized aluminum for hydrophilization. Heller et al. disclose forming lawn type permeation layers by attaching bifunctional linear or polymeric hydrophilic molecules to a metal surface in fabricating a microelectronic device to carry out and control multi-step and multiplex molecular biological reactions in microscopic format, which are significant in clinical diagnostics (see ABSTRACT; COL. 16, lines 55-64). The preferred procedure for producing a lawn type structure involves derivatization of the metal microelectrode surface using aminopropyltriethoxy silane (APS) (see COL. 17, lines 13-15). APS provides a combined permeation and attachment layer with primary amine groups for covalent coupling of binding entities, especially oligonucleotides (see COL. 17, lines 17-19, 38, and 39). APS provides a high level of functionalization in terms of surface binding sites on slightly oxidized aluminum (see COL. 17, lines 20-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

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use oxidized aluminum for hydrophilization as in Heller et al. in the device of Yamada to provide a high level of surface binding sites to bind targeted entities in sample liquid diagnostics.

6. Claims 2-5, 9-14, 16, 26-31, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,399,316 to Yamada in view of U.S. Patent No. 5,942,102 to Hodges et al.

Referring to claims 2, 4, 5, 9-14, 16, 26-28, 30, 31, 33, 34, Yamada discloses a device (10) for withdrawing samples of liquid for analytical elements (see ABSTRACT; FIGURE). The device (10) comprises a carrier (17), detection element, cover (11) with a surface that cooperates with a surface of the carrier (17) to form a capillary-active channel (14), second cover (24), and intermediate layer (12,13) positioned between the second cover (24) and carrier (11) (see FIGURE). Since the instant specification on page 11, lines 4 and 5 discloses that the detection element (2) may be a reagent-impregnated membrane, the detection element may be considered the specific affinity material placed in the reaction region (21) (see COL. 6, lines 55 and 56). The specific affinity material may be chemically or physically bound to at least one surface of the cover (11), intermediate layers (12,13), or carrier (17) (see COL. 6, lines 56-59). Alternatively, an insoluble material to which a specific affinity material is bound may be placed in the reaction region (21) so as not to interfere with the flow of the solution inside the capillary-active channel (14) (see COL. 6, lines 59-63). In this case, one would expect that the insoluble material would have opposite first and second ends with the first end being positioned adjacent to the carrier. Since the specific affinity material is placed in the channel (14), one would also expect that the cover (11) would also cooperate with a surface of the detection element to form the channel (14). After sufficient time has passed for a reaction to occur, a detection unit of a

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measuring apparatus, such as a photoelectron multiplier is located above the carrier (17), which covers the reaction region (21), and the amount of light emitted from the reaction region (21) is measured (see COL. 7, line 67-COL. 8, line 44). In the event one would argue that the specific affinity material is not an element distinct from the cover as shown in the drawings of the instant application, it would have been obvious to one having ordinary skill in the art at the time the invention was made to separate the specific affinity material from the cover since it provides flexibility in testing different assays by allowing placement of different specific affinity material to be placed into the reaction region especially when the device is disclosed as reusable (see COL. 7, lines 26-41). Furthermore, it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art (*Nerwin v. Erlichman*, 168 USPQ 177,179).

The channel (14) has a sample application opening (22) defined by at least one edge (see FIGURE). The channel (14) extends at least from the opening to the second end of the detection element since excess liquid is absorbed by member (28), an ancillary element that may be attached to the end of the channel (14) or second end of the reaction region (21) (see FIGURE). The at least one notch (15,16) in the form of a partial groove is positioned at the at least one edge of the sample application opening (22) of the channel (14) such that one side of the edge of the sample application opening (22) is at least partially interrupted by the at least one notch (15,16) and the surface facing opposite to the at least one notch (15,16) facing the channel (14) is exposed. A liquid sample is contacted with the edge of the sample application opening (22) adjacent to the notch (15,16) such that the liquid sample is immediately transported by capillary



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forces into the channel (14) (see ABSTRACT; FIGURE; SUMMARY OF THE INVENTION; COL. 5, lines 13-31; COL. 6, lines 64-68; COL. 7, lines 1-68; COL. 8, lines 1-9 and 14-36).

Referring to claims 3 and 29, according to Merriam-Webster Collegiate Dictionary, stagger is defined as to arrange in any of various zigzags, alternations, or overlappings of position or time, and alternations is defined as causing to alternate, which is defined as arranged first on one side and then on the other at different levels or points along an axial line or arranged one above or alongside the other. It is noted that the two notches (15,16) are arranged one above or alongside the other depending on the frame of reference and inherently arranged first on one side and then on the other at different levels or points along an axial line, as imperfections inherently exist.

Yamada fails to disclose the at least one notch having a width less than that of the channel. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the at least one notch of Yamada such that the width of the at least one notch is less than that of the channel to provide a small amount of solution to be admitted to the channel or drawn in by wicking or capillary action and allow air to escape as taught by Hodges et al. (COL. 5, lines 3-6, 11, and 12).

7. Alternatively, claims 2 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,399,316 to Yamada in view of U.S. Patent No. 5,942,102 to Hodges et al. as applied to claims 9 and 26, and further in view of U.S. Patent No. 4,439,526 to Columbus.

Referring to claims 2 and 28, Yamada does not disclose at least two notches next to each other. However, in the field of capillary fluid flow, it is known to provide a plurality of access means to the capillary to facilitate fluid flow into the capillary channel. See, for example,

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Columbus, abstract; column 2, lines 29-46 and column 6, lines 63 through column 7, line 2. It would have been obvious to one of ordinary skill in the art to provide at least 2 notches (access means) at the entrance of the channel in the device of Yamada in order to facilitate fluid flow in the channel.

8. Claims 7, 15, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,399,316 to Yamada in view of U.S. Patent No. 5,942,102 to Hodges et al. as applied to claims 9 and 26, and further in view of U.S. Patent No. 6,238,624 to Heller et al.

Referring to claims 7, 15, and 32, Yamada does not disclose using oxidized aluminum for hydrophilization. Heller et al. disclose forming lawn type permeation layers by attaching bifunctional linear or polymeric hydrophilic molecules to a metal surface in fabricating a microelectronic device to carry out and control multi-step and multiplex molecular biological reactions in microscopic format, which are significant in clinical diagnostics (see ABSTRACT; COL. 16, lines 55-64). The preferred procedure for producing a lawn type structure involves derivatization of the metal microelectrode surface using aminopropyltriethoxy silane (APS) (see COL. 17, lines 13-15). APS provides a combined permeation and attachment layer with primary amine groups for covalent coupling of binding entities, especially oligonucleotides (see COL. 17, lines 17-19, 38, and 39). APS provides a high level of functionalization in terms of surface binding sites on slightly oxidized aluminum (see COL. 17, lines 20-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use oxidized aluminum for hydrophilization as in Heller et al. in the device of Yamada to provide a high level of surface binding sites to bind targeted entities in sample liquid diagnostics.

***Response to Arguments***

9. Applicant's arguments with respect to claims 2-5, 7, and 9-34 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan  
Examiner  
Art Unit 1743

eq

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700